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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,262	07/03/2003	Eli Gilboa	1430/13	3315

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,262	GILBOA ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2, 8 and 18 drawn to a method of treating cancer comprising administering an angiogenesis-related antigenic polypeptide, classified in class 424, subclass 184.1 respectively.

II. Claims 3, and 8 drawn to a method of treating cancer comprising administering a nucleic acid encoding an angiogenesis-related antigenic polypeptide, classified in classes 514, subclass 44.

III. Claims 4-5, and 7-8 drawn to a method of treating cancer comprising administering antigen presenting cells pulsed with at least one angiogenesis-related antigenic polypeptide, classified in class 424, subclass 93.1.

IV. Claims 4, 6-9, and 16, drawn to a method of treating cancer comprising administering antigen presenting cells transfected with mRNA encoding an angiogenesis-related antigenic polypeptide, classified in class 424, subclass 93.21.

V. Claims 11-12 and 14, drawn to a composition comprising antigen presenting cells pulsed with an angiogenesis related antigen and further pulsed with a tumor antigen,

VI. Claims 11-12, and 14-15, drawn to a composition comprising antigen presenting cells pulsed with an angiogenesis related antigen and further transfected with mRNA encoding a tumor antigen,

VII. Claims 11-14, drawn to a composition comprising antigen presenting cells transfected with an mRNA encoding an angiogenesis related antigen and further pulsed with a tumor antigen.

VIII. Claims 11-15, drawn to a composition comprising antigen presenting cells transfected with an mRNA encoding an angiogenesis related antigen and further transfected with mRNA encoding a tumor antigen,

IX. Claim 17, drawn to a method of treating cancer comprising administering immune T lymphocytes to a patient generated *in vitro* by contacting the T lymphocytes with antigen presenting cells transfected with mRNA encoding an angiogenesis related antigen and mRNA encoding a tumor antigen, classified in class

Claim 1 links inventions I-IV and claim 10 links inventions V-VIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 1 and 10. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

1) Inventions I -IV are patentably distinct in that the active ingredient to be administered in each of these methods are substantially different in structural, chemical, and functional properties, are made using different techniques, and have different modes of biological activity *in vivo*. Specifically, a polypeptide and an mRNA nucleic acid encoding a polypeptide have substantially different physical and chemical properties and different modes of activity such that the administration of the one is unrelated to the administration of the other. Further, antigen presenting cells pulsed with a polypeptide or transfected with mRNA are structurally and functionally different from the polypeptide or mRNA itself and structurally and functionally different from each other. As such, the search for each method using each of these active ingredients is not co-extensive and it would place an undue burden on the examiner to search and examine these inventions together.

2) Inventions V-VIII are patentably distinct in that cells claimed in each of these compositions are substantially different in structural, chemical, and functional properties and are made using different techniques. Specifically, cells pulsed with a polypeptide versus cells transfected with an

mRNA nucleic acid encoding a polypeptide have substantially different physical and chemical properties and different modes of activity. Also, methods for making cells pulsed with a polypeptide are unrelated to methods for making cells transfected with mRNA as they utilize different reagents and techniques. As such, the search for each of these compositions is not co-extensive and it would place an undue burden on the examiner to search and examine these inventions together.

3) Inventions I-II and Inventions V-VIII are patentably distinct in that the compositions of inventions V-VIII are not required for the methods of inventions I and II which involve the direct administration of polypeptide or mRNA to a patient, not antigen presenting cells. As such, the search for inventions I-II is not co-extensive and it would place an undue burden on the examiner to search and examine these inventions together.

4) Inventions III-IV and Inventions V-VIII are related as product and process of use. The inventions can be shown to be distinct if **either** or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the compositions comprising antigen presenting cells can be used in materially different processes such as the use of the antigen presenting cells to stimulate T cells in *in vitro* cultures.

5) Invention I-VII and Invention IX are patentably distinct each from the other in that neither the antigen presenting cells nor the lymphocytes are present in the compositions of inventions V-VII or the methods of inventions I-III. Further, the methods of inventions IV and invention IX are materially different in that the antigen presenting cells are directly administered *in vivo* in the

methods of invention IV, whereas the antigen presenting cells are used *in vitro* in invention IX and T lymphocytes are administered *in vivo*. Thus, for the reasons stated above, the search for inventions I-VII and IX is not co-extensive and it would place an undue burden on the examiner to search and examine these inventions together.

6) Inventions VIII and Inventions IX are related as product and process of use. The inventions can be shown to be distinct if **either** or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the compositions comprising antigen presenting cells can be used in materially different processes other than stimulating T cells *in vitro* cultures, such as the use of the antigen presenting cells in *in vivo* methods of delivery of the antigen presenting cells to treat cancer.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

This application further contains claims directed to the following patentably distinct species of angiogenesis related antigens:

a) Id1

b) Id3

c) VEGF

d) VEGFR-2

e) angiopoietin

f) Tie-2.

The species are independent or distinct because each protein has unique chemical, structural, physical, and functional properties. As such, the search for each species is unrelated and not-coextensive. Thus, the search and examination of all species together would place and undue burden on the examiner.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER